this section for any required information that is not readily available.

(e) A report submitted by a manufacturer, distributor, or importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, distributor, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer, distributor, or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury.

(f) No report of a correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803, 804, or 1004 of this chapter.

EFFECTIVE DATE NOTE: At 62 FR 67274, Dec. 24, 1997, §806.10 was stayed. This section contains information collection requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 806.20 Records of corrections and removals not required to be reported.

(a) Each device manufacturer, importer, or distributor who initiates a correction or removal of a device that is not required to be reported to FDA under §806.10 shall keep a record of such correction or removal.

(b) Records of corrections and removals not required to be reported to FDA under §806.10 shall contain the following information:

(1) The brand name, common or usual name, classification, name and product code if known, and the intended use of the device.

(2) The model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

(3) A description of the event(s) giving rise to the information reported and the corrective or removal action that has been, and is expected to be taken.

(4) Justification for not reporting the correction or removal action to FDA, which shall contain conclusions and any followups, and be reviewed and evaluated by a designated person.

(5) A copy of all communications regarding the correction or removal.

(c) The manufacturer, importer, or distributor shall retain all records required under this section for a period of 2 years beyond the expected life of the device, even if the manufacturer, importer, or distributor has ceased to manufacture, import, or distribute the device. Records required to be maintained under paragraph (b) of this section must be transferred to the new manufacturer, importer, or distributor of the device and maintained for the required period of time.

EFFECTIVE DATE NOTE: At 62 FR 67274, Dec. 24, 1997, §806.20 was stayed. This section contains information collection requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 806.30 FDA access to records.

Each device manufacturer, importer, or distributor required under this part to maintain records concerning corrections or removals and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by FDA and under section 704(e) of the act, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records and reports.

§ 806.40 Public availability of reports.

(a) Any report submitted under this part is available for public disclosure in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under §20.61 of this chapter; and

(2) Any personnel, medical, or similar information, including the serial numbers of implanted devices, which would constitute a clearly unwarranted invasion of personal privacy under §20.63 of this chapter or 5 U.S.C. 552(b)(6); provided, that except for the information under §20.61 of this chapter or 5 U.S.C. 552(b)(4), FDA will disclose to a patient